

## REMARKS

Claims 34 to 38 remain in the application; claims 29 to 33 stand withdrawn. Claims 34 to 38 stand rejected under 35 USC §103(a) as being unpatentable over Sisley et al (U.S. Patent No. 4,405,313) in view of Wilson et al (U.S. Patent No. 6,638,242). Claim 38 stands rejected under 35 USC §103(a) as being unpatentable over Sisley et al in view of Wilson et al and further in view of Butler (U.S. Patent No. 6,758,854). Claims 34 to 38 also stand rejected under “nonstatutory obviousness-type double patenting” in view of Serial No. 10/974,267. Claim 34 also stands rejected under 35 USC §112, second paragraph, for lacking clarity. Claim 34 is amended hereby to overcome the rejection under Section 112. Paragraph [0036] is amended hereby to update the reference to another application initially copending herewith.

Claim 34 is amended to delete “an initially separate” and to designate the “hub” as a “hub member” (supported by Figures 5 and 6), and to insert “of the first and second catheters” after “proximal end portions” to clarify that the catheter portions extend through the hub. It is believed that these amendments give sufficient clarity to the claim and overcome the rejection.

Reference Sisley et al sets forth a catheter assembly having a dual lumen catheter with a split distal portion and a split proximal portion, with split portions joined longitudinally at fill-in portions 16,18, by cuff 20 and by “splitter” 22, with the splitter 22 being near the proximal ends of the catheter lumens 12,14 which are terminated by fittings 24,26. The fill-in portions join two otherwise separate catheter tubes, as shown in Figure 3, and disallow leakage of blood from the vessel where the catheter exits the vessel through an incision, and a bacterial seal at the proximal exit from the subcutaneous tunnel. At column 5, lines 31 to 36, the reference refers to “a splitter 22 which wraps the junction of the tubes 12 and 14, which separates the tubes 12 and 14, and which eliminates further splitting of the tubes 12 and 14.”

While the splitter of the reference Sisley et al can be appreciated as a “hub” equivalent generally, there is no express or implicit disclosure or suggestion in the reference that the “hub” is a member that is releasably attachable to the catheter tubes 12,14. From the sparse details provided in the reference, the splitter is secured to the catheter assembly during manufacturing thereof by wrapping, and there is no disclosure or suggestion that the splitter is removable from the catheter assembly once so secured. The artisan of routine skill would clearly understand this, that it would be improper to expect the practitioner at the patient’s bedside to apply the splitter, or material that would become a splitter upon application and curing or hardening, to the catheter, especially since adhesive must be used very near open incisions in the patient and which would, while curing, be presumptively and unnecessarily detrimental to the patient’s health and would extend the length of time for the practitioner to perform the entire “wrapping” procedure which also would unnecessarily heighten the risk to the patient by prolonging the procedure. Since the splitter is applied during manufacturing, the location of the splitter along the catheter is fixed and not selectable by the practitioner.

In the presently claimed invention, the hub member is easily securable to the catheters by snap fit and, more importantly, the site is optimally selectable by the practitioner after subcutaneous tunneling of the catheters, who may have to trim the length of the catheter tubes rather than rely on an immediately available extensive inventory of catheter lengths needed to address needs of different patients. Further, the hub member is releasable from the catheter should it become necessary to repair the catheter: the present invention also provides for repair of catheters that have already been implanted into a patient, without removing a damaged catheter from the patient and re-implanting a new one, causing accompanying distress and risk to the patient. Reference is made to the Specification at paragraphs [0006] to [0008] and [0057] and

[0059]. Thus, the presently claimed invention is a greatly advantageous breakthrough in catheter implantation and repair procedures.

Reference Wilson et al has been discussed and distinguished in the previous Response dated January 19, 2007. This reference does not provide for its hub to enclose proximal portions of its catheter as they pass through the hub; contrarily, the hub encloses distal ends of the extension tube assemblies, and is attachable to a proximal end of the (non-split) dual-lumen catheter using a connection cover and compression sleeve. At column 4, lines 7 to 36, the reference discloses the hub to be formed around cannulae 22,24 whose proximal ends have been inserted into distal ends of the extension tubes 26,28 and with distal ends of the cannulae extending distally from the formed hub body for eventual insertion into lumens of the catheter proximal end. Such forming is a step in manufacturing the hub assembly. The hub is not releasably connectable around proximal end portions of a pair of catheters such that they extend through the hub, as in the presently claimed invention. The reference fails to meet the limitation that the hub be releasably connectable to and around the catheter proximal end portions such that they extend proximally from the hub.

Further, the combination of the disclosure of Wilson et al with that of primary reference Sisley et al, is not appropriate for supporting the rejection of the claims. There is no reason nor suggestion found in either reference for such combination, since more than mere modification of the primary reference would be involved, for no seeming benefit. It is clear that the combination is made by the Examiner using impermissible hindsight, using the Applicants' disclosure as a blue print. It is also clear that the combination would not result in the presently claimed invention, since the hub assembly of Wilson et al must be applied to the end of the catheter.

With regard to claim 35, the cross-sectional shape of the lumens of the catheter of Wilson et al is D-shaped and not circular, and the hub's cannulae require that the cross-sectional shape of the catheter lumens to which it is applied, must also be D-shaped and not circular. Regarding claim 36, there is no disclosure in either reference of a transition between different cross-sectional shapes of the respective catheter lumens. With respect to claim 37, there is no disclosure that the non-split portions of the catheters of either reference, be further splittable beyond the split portions respectively disclosed.

With respect to the rejection of claim 38 under 35 USC §103(a) as being unpatentably over Sisley et al in view of Wilson et al and further in view of Butler (U.S. Patent No. 6,758,854), reference Butler has been discussed before. The Office Action asserts that "the first and second intermediate sections of the first and second catheters 12, 14 are splittably joined to each other." However, reference Sisley et al specifically teaches that the fill-in portions 16,18 bounding the split (not splittable) catheter portions, are to prevent the bound sections from being split. Hence, the intermediate sections are not "splittable" and Applicants respectfully traverse the assertion. Claim 38 depends from claim 37 which is believed to be allowable.

Claims 34 to 38 stand rejected for "nonstatutory obviousness-type double patenting" in view of the claims of pending but later-filed continuation-in-part application Serial No. 10/974,267. The Office Action asserts that the Specification of the pending application "admits" that the hub may be omitted. This assertion is totally improper. Firstly, the Specification portions (including paragraph [0036] hereof) cited have nothing to do with the limitations of the claims of the referred-to pending application being compared with the now-pending claims hereof, which must be the basis on which this rejection must be made. In manner of explanation of the "admission" in paragraph [0036], the comment was relevant to claim 1 as originally filed (but

which claim has since been cancelled), since claim 1 did not have a limitation of a hub; Applicants will delete the comment in paragraph [0036] should the Examiner so advise. Secondly, a referral to the "omission" of an item is certainly not an equivalent of releasably and removably connecting such an item, and since the hub member is a limitation of the present claims, such other statements are inappropriate for use in supporting this rejection. Applicants respectively traverse this rejection. Applicants have exhaustively presented arguments in the previous Response to clearly explain why the rejection should be withdrawn. Applicants respectively refer again to those arguments. In fact, the Office Action's assertions actually support patentability of the present invention, since the requirement of a hub is a limitation not found in the claims of the referred-to pending application and as such the presently pending claims hereof distinguish over the claims thereof.

The claims are believed to distinguish patentably over the prior art, and allowance thereof is respectfully urged. No new matter has been entered hereby, and no amendments to the claims have been entered that would necessitate further search nor raise new issues. If any additional fees are due, please charge same to Deposit Account No. 50-2434.

Respectfully Submitted,

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Date

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